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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,728

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Hiroshi Tsutsui

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WENDEROTH, LIND & PONACK, L.L.P.

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EXAMINER

PHONGSVIRAJATI, POONSIN

ART UNIT

PAPER NUMBER

4176

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,728	Applicant(s) TSUTSUI ET AL.	
	Examiner SIND PHONGSVIRAJATI	Art Unit 4176	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20040930</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-15 fail to satisfy the requirements for statutory subject matter eligibility because they are considered to be drawn merely to the production and/or manipulation of non-functional descriptive material, effecting no “useful, concrete, and tangible result.” It has been held that such claims, even if the non-functional descriptive material is claimed in combination with a computer-readable medium, are considered to comprise non-statutory subject matter, for merely manipulating an abstract idea. In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994).

Moreover, claim 15 is drawn to a computer program per se. Computer programs per se intrinsically require no tangible physical structure, thus do not constitute tangible physical articles or other forms of matter. Therefore, computer programs per se are not considered to be statutory subject matter. To be statutory, a computer program must be: (1) coupled with or combined with some statutory physical structure, and, (2) produce or effect some useful, concrete, and tangible result. See MPEP § 2106.01.

Claim Rejections - 35 USC § 112, Second Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 - 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claimed language reciting “a predetermined biological characteristic” and “indicating predetermined electric quantity” are indefinite to the Examiner, the terms lead to confusion over the intended scope of the claim. The Examiner is unclear from where the biological characteristic or electric quantity is predetermined. For purposes of examination, the Examiner will exclude the term, “predetermined,” for clarification purposes.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2-11 and 14 are rejected under 35 U.S.C. 102(e) as being unpatentable over Causey (US 2002/002326 A1).

7. As to **Claim 2 and 14**, Causey teaches a health care data acquisition system and method comprising a data measuring apparatus for measuring a biological characteristic of a subject and a data management apparatus for managing data of said characteristic, said data measuring apparatus and data management apparatus being connected to each other via a network (Causey, Abstract), wherein said data measuring apparatus includes:

- a characteristic conversion unit operable to convert a characteristic of a subject into information indicating predetermined electric quantity (Causey, paragraphs 8-10); and
- an information transmission unit operable to transmit the information indicating the electric quantity to said data management apparatus (Causey, paragraphs 61-63), and

said data management apparatus includes:

- a reception unit operable to receive the information from said data measuring apparatus (Causey, paragraph 63, Fig.1 element 12);
- a data conversion unit operable to convert said electric quantity into data which is added with a unit indicating the biological characteristic of the subject, based on said received information (Causey, paragraphs 76-78); and a
- a return unit operable to return said converted data to said data measuring apparatus. Causey does teach a return unit operable to return said converted data to said data measuring apparatus (Causey, paragraph 96 and Fig. 29).

8. As to **Claim 3**, Causey teaches the health care data acquisition system according to claim 2, wherein said characteristic conversion unit has:

- a conversion unit including a sensor which converts said characteristic into a predetermined electric quantity (Causey, paragraphs 8-10); and
- an interface unit including a measuring unit for producing information which indicates said converted electric quantity, wherein said sensor and said measuring unit are respectively corresponded with property information indicating respective attribute (Causey, paragraph 90),
- said characteristic conversion unit further specifies said property information, said information transmission unit further transmits said predetermined property information to said data management apparatus (Causey, paragraphs 7-10), and said data conversion unit of said data management apparatus converts said property information into health care data taking said property information into account (Causey, paragraphs 78-80, 87, 98).

9. As to **Claim 4**, Causey teaches the health care data acquisition system according to claim 3, wherein said data conversion unit of said data management apparatus performs said conversion based on calibration curve data which relates said predetermined electric quantity to said characteristic of the subject (Causey, paragraphs 80 and 83).

10. As to **Claim 5**, Causey teaches the health care data acquisition system according to claim 4, wherein said data management apparatus further includes a memory unit operable to memorize calibration curve data corresponding to said property information, and said data conversion unit selects calibration curve data from said memory unit, according to said property information, and performs said conversion based on the selected calibration curve data (Causey, paragraph 83).

11. As to **Claim 6**, Causey teaches the health care data acquisition system according to claim 5, wherein said memory unit memorizes calibration curve data which corresponds to a pair of said property information of the sensor and said property information of the measuring unit (Causey, paragraphs 83 and 104).

12. As to **Claim 7**, Causey teaches the health care data acquisition system according to claim 6, wherein said data management apparatus further includes a direction reception unit operable to receive a direction from an operator (Causey, paragraphs 11, 23, 64, 69, and 80), and said memory unit further memorizes new calibration curve data which corresponds to a pair of new property information of said sensor and new property information of said measuring unit, based on said direction operator (Causey, paragraphs 80 and 83).

13. As to **Claim 8**, Causey teaches the health care data acquisition system according to claim 7, wherein said property information of the sensor is an ID number capable of specifying a current sensor (Causey, paragraph 22, the Examiner takes the position that it is inherent the radio frequency used to communicate information from the

sensors to other receiving devices contain equipment and sensor ID information, since the receiving device must interpret where the data is being sent from), and said property information of the measuring unit is an ID number capable of specifying a current unit (Causey, paragraphs 22 and 68).

14. As to **Claim 9**, Causey teaches the health care data acquisition system according to claim 7, wherein said property information of the sensor indicates at least one of the following information: a type of body fluid which is a measuring subject of the current sensor, a manufacturing number or a manufacturing lot number of a measuring unit which matches the current sensor, and a valid period of the current sensor (Causey, paragraphs 22-25, 61-68, and 71).

15. As to **Claim 10**, Causey teaches the health care data acquisition system according to claim 7, wherein said property information of the measuring unit indicates at least one of the following information: a type of body fluid which is a measuring subject of the current measuring unit, a manufacturing number or a manufacturing lot number of a sensor which matches the current measuring unit, and a valid period of the current measuring unit (Causey, paragraphs 22-25, 61-68, and 71).

16. As to **Claim 11**, Causey teaches the health care data acquisition system according to claim 2, wherein said data management apparatus further includes:

- a first detection unit operable to detect that said data measuring apparatus has transmitted the information to said data management apparatus (Causey, paragraph 76);

- a second detection unit operable to detect that said data management apparatus has transmitted the health care data to said data measuring apparatus(Causey, paragraph 87 or 94); and
- a charging unit operable to charge a predetermined amount to at least one of said data measuring apparatus and said data management apparatus in the case where each of said transmissions is detected by said first detection unit and said second detection unit (Causey, Fig. 25 element 1008 and paragraph 100).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 1, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi (WO/2001/093143) in view of Causey (US 2002/002326 A1).

20. As to **Claim 1, 13, and 15**, Doi teaches a data measuring apparatus, method, and program for measuring a predetermined biological characteristic of a subject (Doi, Abstract), the apparatus including:

- a characteristic conversion unit operable to convert a characteristic of a subject into information indicating predetermined electric quantity (Doi, pg. 5 paragraphs 1-3 and pg. 6 paragraph 28 of Full Contents);
- an information transmission unit operable to transmit the information indicating the converted electric quantity to another predetermined apparatus (Doi, pg. 9 of Full Contents); and

But Doi does not specifically disclose a data reception unit operable to receive, from said another apparatus, data which is added with a unit indicating the biological characteristic of the subject. Causey does teach a data reception unit operable to receive, from said another apparatus, data which is added with a unit indicating the biological characteristic of the subject (Causey, paragraph 96).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the function to display results and characteristic trends of a patient with the measurement device of Doi. One would be motivated to display the results to a portable device in order to inform the patient by way of convenience.

21. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey (US 2002/002326 A1).

As to **Claim 12**, Causey teaches the health care data acquisition system according to claim 11, as applied above under the rejection under 35 U.S.C. 102(e), wherein a first detection unit, a second detection unit, and a charging unit (Causey, paragraphs 76,87, 94, Fig. 25 element 1008), but does not specifically disclose each of the said first detection unit, second detection unit, and charging unit further calculating the number of times the information has been transmitted. However, the Examiner takes official notice that it is well known to those of ordinary skill in the art that a computer may count the number of times a data measuring apparatus transfers data to a computer or vice versa. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Causey so as to store the number of times data has been transferred from the data measuring apparatus to the computer, in order to keep track of the number of times medical data has been transferred to a data management apparatus such as a computer.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIND PHONGSVIRAJATI whose telephone number is (571) 270-5398. The examiner can normally be reached on Monday - Thursday 8:00am-5:00pm (ET).

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. P./
Examiner, Art Unit 4176
July 23, 2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 4176